

Ian Chalmers
Chief Executive

14 July 2008

Mr Elton Humphery
Secretary
Community Affairs Committee
Department of the Senate
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Mr Humphery

I am pleased to present Medicines Australia's submission to the Australian Senate Community Affairs Committee review of the *National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2008*. Medicines Australia welcomes this inquiry.

Medicines Australia represents the innovative medicines industry in Australia. Our member companies comprise more than 80 percent of the prescription pharmaceuticals market and are engaged in the research, development, manufacture, supply and export of prescription medicines. As such, Medicines Australia is an important partner in any policy that affects the regulation, manufacture, distribution and utilisation of pharmaceuticals in Australia.

Medicines Australia recommends that the Senate rejects legislation enabling the introduction of cost-recovery arrangements associated with the listing of medicines on the Pharmaceutical Benefits Scheme and designation of vaccines on the National Immunisation Program.

Medicines Australia opposes introduction of the proposed cost-recovery arrangements because they:

1. have the potential to restrict access to medicines for some Australians, most importantly children, cancer sufferers, the dying and Aboriginal and Torres Strait Islanders, thus contradicting Australia's National Medicines Policy;
2. are not accompanied by any proposals and/or performance targets to ensure improvement in the efficiency or timeliness of the PBS listing process;
3. are likely to deter innovation in the Australian pharmaceutical industry by creating additional barriers to investment in an industry that, as recent Productivity Commission reports have shown, is already one of the most heavily regulated in Australia; and

4. do not conform to the standards and requirements contained in the Australian Government's Guidelines on cost-recovery arrangements.

In addition to the arguments provided in the submission, Medicines Australia has been invited to present its view to the Community Affairs Committee on 28 July 2008. I have accepted this invitation and welcome the opportunity to discuss further a proposed policy that Medicines Australia does not believe to be in the best interests of the Australian community.

Yours sincerely

A handwritten signature in black ink, appearing to read 'I. Chalmers', written in a cursive style.

Ian Chalmers

Submission

**Australian Senate Community Affairs Committee
Inquiry into the *National Health Amendment
(Pharmaceutical and Other Benefits –
Cost Recovery) Bill 2008***

July 2008

Medicines Australia submission to the Australian Senate Community Affairs Committee Inquiry into the *National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2008*.

Executive Summary

Medicines Australia is opposed to the introduction of the proposed cost-recovery arrangements for the listing of medicines on the Pharmaceutical Benefits Scheme and designating vaccines on the National Immunisation Program.

Medicines Australia believes that:

- the introduction of the proposed cost-recovery arrangements has the potential to restrict access to medicines for Australians. The proposed arrangements will act as a disincentive for companies to seek PBS listings for low volume medicines, with the unintended consequence that some patients will miss out on certain medicines. The risk is most evident for non-orphan medicines used in paediatric, palliative and oncology settings, and for those targeting Aboriginal and Torres Strait Islander populations.
- the introduction of the proposed cost-recovery arrangements are not accompanied by any proposals and/or performance targets to ensure improvement in the efficiency or timeliness of the PBS listing process; the Bill provides no mechanism for fees collected to be adjustable /available to fund process improvements and/or other efficiencies in the PBS listing process.
- the introduction of the proposed cost-recovery arrangements may deter innovation in the Australian pharmaceutical industry by creating additional barriers to investment in an industry that, as recent Productivity Commission reports have shown, is already one of the most heavily regulated in Australia. The proposal conflicts with the objective of encouraging greater investment in Australia by the pharmaceuticals industry.
- the pharmaceuticals industry has already delivered significant savings to the Australian government through the 2007 PBS Reforms (\$3 billion over ten years). The additional financial impost at this time of significant change undermines business certainty.
- the proposed cost-recovery arrangements, and the process leading up to the introduction of the Bill, do not meet the standards and requirements contained in the Australian Government's Guidelines on cost-recovery arrangements. More consultation with key stakeholders was required and would have highlighted all of the issues outlined in this submission. Importantly, Medicines Australia is not aware that either a Cost-recovery Impact Statement or a Regulatory Impact Statement has been developed as required prior to the introduction of "significant cost-recovery arrangements".

For these reasons, and others discussed below, **Medicines Australia recommends:**

that the Senate reject the *National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2008*

1. Introduction

Medicines Australia represents the innovative medicines industry in Australia. Our member companies comprise more than 80 percent of the prescription pharmaceuticals market, and are engaged in the research, development, manufacture, supply and export of prescription medicines.

The pharmaceuticals industry is a key industry in Australia which provides benefits to both Australians' health and the health of Australia's economy. Companies in this sector are constantly working to bring new and effective medicines to patients and invested around \$752 million in local research and development in 2005-06

As a principal stakeholder, Medicines Australia (MA) welcomes the opportunity to present its position to the Australian Senate Community Affairs Committee's review of the *National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2008*.

This legislation seeks to introduce cost-recovery arrangements for the listing of medicines on the Pharmaceutical Benefits Scheme (PBS) and designating vaccines on the National Immunisation Program (NIP). The total cost to Government of the listing process is estimated to be about \$14 million per annum. The Government proposes to recover this cost through the imposition of fees when companies lodge submissions for listing on the PBS and NIP. (Hereafter, this document refers only to the PBS for the sake of convenience).

The proposed fee structure, as understood by Medicines Australia, is:

Major submission	\$119 500
Minor submission	\$12 500
Secretariat listing	\$1 000
Generic products	\$500
Pricing arrangements	\$25 000

This means that a sponsor could face fees of up to \$145,000 to get a medicine listed on the PBS. This is in addition to the considerable costs that a company already assumes in the preparation of a submission to the PBAC and does not take into consideration the cost of major resubmissions that are commonly required to secure reimbursement.

Medicines Australia opposes the introduction of the proposed arrangements for the reasons described in this submission. This submission will provide comment on the proposal against each of the inquiry's Terms of Reference. It

will also highlight that the proposed arrangements, and the lead-up to the introduction of the Bill, do not meet the standards and requirements of the Australian Government's own cost-recovery guidelines.¹

2. The PBS and the function of the PBS Listing Process

The PBS is an integral part of Australia's tax-payer funded, universal health system. It ensures that medicines are available to all Australians regardless of ability to pay, and it reflects the Australian government's long-term commitment to achieving both equity in access to health services and equity in health outcomes. This role of the PBS is explicitly recognised in Australia's National Medicines Policy, in particular in its objective to provide "[t]imely access to the medicines that Australians need, at a cost individuals and the community can afford."² As part of Australia's health system the PBS complements the Medicare Benefits Schedule, which lists health services and procedures that are subsidised by taxpayers.

Under Australian law, the decision to subsidise a particular medicine by listing it on the PBS is the prerogative of the Commonwealth Minister for Health and Ageing (although Cabinet approval is required if the total cost to the taxpayer of any decision is expected to be greater than \$10 million per annum). The Pharmaceutical Benefits Advisory Committee (PBAC) is established under the *National Health Act 1953* to recommend to the Minister for Health and Ageing which drugs, medicinal preparations and (since 2006) vaccines should be listed on the PBS.

It is important to emphasise that a positive PBAC recommendation does not automatically result in a listing on the PBS. This decision lies with the Minister.

In formulating its recommendation to the Minister, the PBAC takes into consideration a medicine's clinical- and cost-effectiveness relative to medicines already available on the PBS. The information required to make this recommendation is provided in a submission to the PBAC by a sponsor, usually a pharmaceuticals company. This submission contains detailed analysis of clinical trial data and complex economic modelling to meet the

¹ Commonwealth of Australia (2005) *Australian Government Cost Recovery Guidelines*, Canberra.

² The Australian Government, Department of Health and Ageing (2000) *The National Medicines Policy*. Available at [www.health.gov.au/internet/main/publishing.nsf/Content/nmp-objectives-policy.htm/\\$FILE/nmp2000.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/nmp-objectives-policy.htm/$FILE/nmp2000.pdf)

The four central objectives of Australia's National Medicines Policy are:

- timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry.

stringent requirements to establish both the relative clinical effectiveness and cost-effectiveness of a medicine.

During the PBS listing process, this submission is evaluated by a mix of Departmental officials, independent evaluators and expert committees, all of which provide advice to the PBAC for the purposes of formulating its recommendation to the Minister.

The PBS listing process is designed to provide information to the Australian government on how best to target its resources within the Australian health care system to get the best health outcomes.

Whilst Medicines Australia supports the role of appropriate health economics analysis as a mechanism to promote the efficient allocation of scarce taxpayer-funded health resources, it questions whether the cost of a government process designed to achieve this should be borne by the private sector through cost-recovery arrangements. It is important to note that the structure of pharmaceuticals market in Australia is completely determined by this policy level decision to provide subsidised health care to the Australian community. The private (i.e. unsubsidised) market for pharmaceuticals is limited.

For this reason, Medicines Australia does not believe that the oft-cited comparison of the proposed PBS cost-recovery arrangements with those that operate for the TGA is appropriate.

The TGA processes concern the decision of private sector companies to seek regulatory approval for the marketing of a product in Australia. Before a medicine can be sold in Australia, companies must demonstrate to the TGA that a medicine is both safe and efficacious for use by patients. The PBS, however, is a Government program established to provide tax-payer subsidised health care. The PBS listing process is designed to assist the government choose which medicines it wishes to subsidise.

In this sense the appropriate analogy for the purposes of cost-recovery arrangements is the **Medicare Benefits Schedule (MBS)**. The Australian Government, quite rightly, does not charge medical practitioners for lodging submissions to have their services subsidised under the MBS even though the latter stand to benefit from this. It is inconsistent for the Government to seek to impose fees on companies for a process that the Government has designed so that it receives the information required to decide which medicines it wishes to subsidise. Companies are no more the principal beneficiaries of the PBS listing process, than medical practitioners are of MBS items; whilst both systems determine the structure of the market for products and services, this structure is designed with the patient as the principal beneficiary

3 Inquiry Terms of Reference

Medicines Australia is pleased to provide its view on each of Terms of Reference, against which the Senate Committee has been asked to report.

(a) the impact of the Pharmaceutical Benefits Scheme (PBS) cost recovery on:

(a) (i) patients' timely and affordable access to medicines:

Medicines Australia believes that the proposed cost-recovery arrangements are likely to have a detrimental effect on patients' timely and affordable access to medicines, which is a key objective of Australia's National Medicines Policy.³ This is because the additional fees will act as a strong disincentive to seeking listings for medicines/indications where there is demonstrated clinical need. This is particularly true for products where there is already limited commercial viability. This highlights the previous point that the PBS exists for non-commercial reasons. Cost-recovery arrangements will introduce an added financial/commercial consideration when there should not be one in an arrangement designed with the patient as the principal beneficiary.

To be listed on the PBS, a company must provide high-level evidence establishing both clinical effectiveness and relative cost-effectiveness. The price received by companies follows an assessment by the PBAC as to relative value of a medicine as defined by the health outcomes that it produces for a defined condition. It is important to note that this goes beyond what is required to register a medicine for use in Australia and what is required in many comparable countries. Pharmaceutical companies already face considerable expense in the preparation of major submissions to the PBAC. Medicines Australia's best estimates of the direct cost is a range between **\$150,000 to \$500,000** depending upon the complexity of the submission.

The cost of the existing process, including the 30 per cent chance of rejection and requirement for resubmission (discussed in the next section), means that pharmaceutical companies already face difficult decisions about which medicines to put forward to the PBAC. There are already some medicines for small patient populations where companies have not sought PBS listing due to the high cost of lodging a submission; cost recovery will exacerbate existing high cost barriers to submissions.

With the addition of cost recovery fees, Medicines Australia believes that the risk to access is greatest for:

- additional indications for existing products;

³ The Australian Government, Department of Health and Ageing (2000) *The National Medicines Policy*. Available at [www.health.gov.au/internet/main/publishing.nsf/Content/nmp-objectives-policy.htm/\\$FILE/nmp2000.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/nmp-objectives-policy.htm/$FILE/nmp2000.pdf)

- small disease or population groups, such as those used in the paediatric, palliative and oncology settings;
- “orphan” drugs or those products used at the later stages of disease – sometimes described as products matching a “rule of rescue”;
- medicines/indications that are listed for the purposes of meeting the healthcare needs of Australia’s Aboriginal and Torres Strait Islander (ATSI) population.

It is worth noting that the PBAC already considers children, indigenous populations and the dying as under-served by existing processes. The Government has established the Paediatrics Medicines Advisory Group, the ATSI Medicines Advisory Group and the Palliative Care Medicines Advisory Group to work with and encourage pharmaceuticals companies to register and list medicines (or formulations of medicines) for small, but important indications. The work of these Committees will be only made more difficult by the proposed Bill.

Importantly, Medicines Australia does not believe that provisions to provide a fee-waiver for certain submissions will be sufficient to overcome these concerns, as the system is already replete with significant disincentives for the listing of medicines for such groups. In addition to the direct costs associated with preparing a submission, the opportunity costs of choosing to prepare a listing submission for one product over another needs also to be factored into any real understanding of the process (especially where small population medicines are concerned).

Medicines Australia argues that access to medicines will be further undermined by the introduction of cost-recovery due to another underappreciated feature of the current system. The exclusively *ex-ante*⁴ nature of the assessment process means that the evidence-base for most medicines is often “immature” when a listing is first sought by a company. Indeed, it often takes many years for a comprehensive evidence-base for a medicine to be established.

In order to get a medicine listed, a company will often initially seek a highly restricted listing that accords with the evidence that is available at the time. Over time, as more comprehensive data and evidence are gathered, a company will apply to the PBAC to expand a restriction or indication in line with the emerging evidence (a process that typically lags behind actual clinical practice). Usually this results in more Australians gradually getting access to needed medicines as the clinical and cost-effectiveness of the use of such medicines for additional indications is established.

Whether a company continues to seek listing changes in line with the emerging evidence base and best clinical practice will depend on the

⁴ This refers to the requirement that medicines are first fully assessed for clinical and cost-effectiveness before they are subsidised. This is not a requirement in all comparable countries. In the UK, for example, a new medicine is subsidised at launch and is subject to a health technology assessment by the the National Institute for Health and Clinical Excellence (NICE) only after the medicine has been used in the community for a period of time. This allows time for the evidence base to mature in the context of real-world clinical practice.

marginal commercial benefit of seeking such an alteration and especially whether a medicine is operating in a generic market where a company is exposed to free-riding behaviour.

The costs for companies in preparing a major submission are already significant, the effect of adding additional disincentives to preparing a submission will potentially result in a growing gulf between listing indications /restrictions and the best available evidence for clinical practice. This in turn translates to reduced access to medicines for Australians.

A real-world example illustrating this problem is provided in Box 1.

Other areas likely to be affected by the proposed cost-recovery arrangements for analogous reasons are:

- medicines that achieve TGA registration based on early (Phase II) clinical trial data – most notably breakthrough oncology medicines – may be delayed because of uncertainty in the data or evidence-base; and
- new formulations that improve delivery, patient compliance and health outcomes but for which the company may not recover the costs of gaining a PBS listing, especially where the product is nearing the end of patent life.

(a) (ii) the Australian pharmaceutical industry:

The Australian pharmaceuticals industry will respond to the proposed cost-recovery arrangements as any commercial concern would to increases in costs relating to government regulations and charges. In this case, the overwhelming incentive for pharmaceutical companies is to put resources only into seeking listings for medicines for which there is both a compelling business case and for which the evidence-base is sufficiently complete to minimise the possibility of rejection by the PBAC. In short the incentives introduced by the cost-recovery Bill will favour either delayed listing **or** no listing - especially where this concerns small population or late patent life-cycle listings.

Medicines Australia believes that the suggestion that there will be a reduction in the number of re-submissions to the PBAC as a result of imposing user-pay fees is misguided. The data show that only 30 per cent of first time submissions are given a positive recommendation by the PBAC. The average number of resubmissions required to secure a positive recommendation is in fact two or three (each of which would be subject to proposed cost-recovery fees – i.e. up to \$383,500 including pricing). This expensive and inefficient cycle of resubmissions to the PBAC, however, is **not** driven by poor quality submissions or a lack of financial discipline on companies' decision to lodge a submission. Moreover, the cost recovery proposal contains no measures to reduce the resubmission rate.

The evidence indicates that resubmissions result from uncertainty in the interpretation and translation of data and evidence presented in a submission as it relates to decision-making. The importance of this is evidenced by the

Box 1 – Effects of Cost-Recovery on Expanded Indication Listings

Alendronate sodium is a bisphosphonate registered with the TGA for use in the i) treatment of confirmed osteoporosis, ii) prevention of osteoporosis in postmenopausal women with low bone mass and patients on long-term corticosteroids, and iii) treatment of Paget's disease. The PBS listing for alendronate sodium is restricted to patients over 70 years of age or older with a BMD (Bone Mineral Density) T-score ≤ -3.0 , or patients with confirmed osteoporosis and a fracture due to minimal trauma, as well as the treatment of patients with Paget's disease.

Alendronate sodium was originally marketed in Australia by Merck Sharp & Dohme (MSD), with expiration of its patent in 2005 leading to generic versions of this medicine also being supplied by Apotex, Arrow, Bellwether and Ranbaxy.

MSD recently applied to the PBAC to broaden the PBS listing for alendronate sodium to allow use in the treatment of patients aged 70 years of age or older and with a BMD T-score ≤ -2.5 . This would have brought the PBS listing for alendronate into line with current clinical guidelines and its TGA indication specific to confirmed osteoporosis. At its March 2008 meeting, the PBAC rejected MSD's application "because of concerns of a less favourable ratio of harms to benefits in this wider population and an unacceptable cost-effectiveness ratio".

Under normal circumstances, a company such as MSD might consider lodging a resubmission with the PBAC to address its concerns. However, under cost-recovery, there would be limited incentive for MSD, or any of the generic companies who supply alendronate sodium, to resubmit this application given that alendronate sodium is subject to considerable generic competition. If MSD is unable to resubmit, an estimated 175,000 men and women with osteoporosis over the age of 70 will not receive PBS access to this medicine should PBS cost recovery be implemented.

priority that the high level Access to Medicines Working Group⁵ has assigned this issue.

Medicines Australia maintains that the cost of preparing a submission to the PBAC already serves as an effective disincentive to making poor or frivolous submissions for the listing of medicines; it is unlikely that the *marginal* (i.e. additional) effect of the proposed cost-recovery fees will be to reduce the number of re-submissions.

Exacerbation of existing "Free Rider Effects"

Under the proposed cost-recovery arrangements, there is a significant risk that existing "free-rider" effects will be magnified. Due to the "public good" characteristics of the PBS listing process (i.e. the non-excludability of a submission evaluation that informs the decision-making process), generic

⁵ The Access to Medicines Working Group is a peak working group of the Department of Health and Ageing and Medicines Australia. The AMWG is an initiative that forms part of the PBS reform package announced in November 2006 and is tasked with reviewing the process of listing new medicines in Australia.

companies can “free-ride” on earlier submissions and assessments of medicines. Under the current proposal an innovator company will be charged \$145,000 to get a medicine listed on the PBS, assuming the submission is accepted first time round. This is in addition to the significant costs related to preparing the submission and presenting evidence to establish both the relative clinical and cost-effectiveness of a medicine. A follow-up company not only free-rides on the cost of establishing the evidence-base, it then free-rides on the complex assessment of this submission as paid-for by the innovator company. As it is proposed, a generic company will be liable for only \$500 to get its product listed on the PBS. The cost recovery arrangements exacerbate the marked disparity in the cost of entry for products that compete for market share.

This has implications for listing decisions made by companies for products nearing patent expiry.

Medicines Australia notes that the Australian Government’s cost-recovery guidelines state that “free-rider” effects should be taken into consideration when an agency is considering the appropriateness of introducing cost-recovery arrangements.

(a) (iii) New products and innovation

Innovation is a key focus for the new Government. The Minister for Innovation, Industry, Science and Research, Senator Kim Carr has initiated a Review of the National Innovation System to examine the various innovation and industry programs available across Australia as well as manufacturing, skills shortages. More significantly for the pharmaceuticals sector, Minister Carr has announced the formation of a Pharmaceuticals Industry Strategy Group (PISG). This group, the PISG, has been charged with developing a plan to attract investment in pharmaceutical R&D, clinical trials and manufacturing activity to present to Minister Carr by the end of 2008. Minister Carr's announcement in relation to the PISG recognises the global nature of the industry, the rationalisation which is occurring and the impact of regulatory and reimbursement systems.

In terms of the Government's active pursuit of innovation and innovative industries, the proposed cost recovery policy clearly undermines this objective. Rather than encouraging greater investment in Australia by the pharmaceuticals industry, companies face the prospect of paying a fee when seeking to introduce a new medicine to Australia – a requirement that no other government around the world has in place.

The pharmaceuticals sector in Australia is already facing some major challenges in maintaining and attracting new investment. The industry has recently seen several Australian manufacturing plants close, job losses, lower investment levels and the growth in R&D expenditure is not keeping pace with worldwide trends. The Australian industry also faces fierce regional competition for global investment from rapidly growing markets that have increasing quality in R&D (such as China and India).

Medicines Australia believes the cost recovery policy will exacerbate negative perceptions about Australia's reimbursement system and this is reasonably expected to have an adverse impact on investment, employment, exports and research in Australia in the long term.

(a) (iv) the independence of the Pharmaceutical Benefits Advisory Committee

Medicines Australia supports Australia's system of cost-effectiveness evaluation of medicines, the PBAC and its independence. A robust evaluation system ensures that the medicines Australians receive through the PBS are cost-effective and deliver value for money.

The PBS and its evaluation systems are a government mechanism designed, first and foremost, as a social policy instrument to ensure Australians get affordable access to the medicines they need. The introduction of cost recovery from companies for this process runs the risk of creating a perception in the minds of some that the PBS exists for something other than Australian patients.

Perceptions about the industry, the independence of the PBAC and the confidence of the community about the independence of this process are important. The introduction of any policy measure should not inadvertently undermine confidence in the process or contribute to confusion about its objectives.

(b) cost recovery mechanisms in other countries.

Medicines Australia has contacted its counterparts in Europe, Asia and North America and asked whether any comparable country has a cost-recovery or "cost recovery-like" arrangement for the listing of medicines to be reimbursed/ covered by a taxpayer funded health system.

To the best of Medicines Australia's knowledge, no other comparable country imposes any form of cost-recovery mechanism or any system that charges companies for applications for government reimbursement.

(c) how cost recovery will improve the timeliness and effectiveness of the current PBS process for listing new medicines;

There is no indication that the proposed cost-recovery arrangements will improve the timeliness and effectiveness of the current PBS process for listing new medicines.

The Bill proposes that fees collected will flow into general consolidated revenue (as in effect a levy or tax) and not be adjustable/available to fund process improvements and/or other efficiencies in the PBS listing process itself. There are no accompanying proposals to reduce the high number of resubmissions currently often required to get a medicine listed on the PBS. In

fact, as already discussed the proposal is likely to worsen the timeliness of listing some medicines.

Medicines Australia notes that the cost-recovery guidelines state that whether the introduction of cost-recovery arrangements are cost-effective should be taken into consideration when an agency is considering the appropriateness of introducing such arrangements. Medicines Australia argues that the current proposal *a priori* rejects this possibility as the cost-recovery arrangements are not accompanied by any proposals and/or performance targets to ensure improvement in the efficiency or timeliness and also do not allow for submission fees to be used to generate further efficiencies and improvements.

(d) the modelling and consultation underpinning the decision.

Medicines Australia is disappointed at the inadequate and disjointed consultation on the development and introduction of the proposed cost-recovery arrangements.

The previous government announced its intention to introduce PBS cost-recovery in the 2005-06 Budget. However, the only point of consultation with the industry regarding the proposal came in May 2007 when Medicines Australia was invited at this time to make a written submission to the Department of Health and Ageing's (DoHA) discussion paper *Approach to PBS Cost Recovery Charges*.

The DoHA discussion paper sought input only on the form of cost-recovery implementation and *not* on the proposal itself. No consultation was invited on the appropriateness of applying cost-recovery to the PBS listing process.

Medicines Australia submitted a response to that discussion paper noting that:

- the period provided for responses was insufficient;
- the level of detail provided in the DoHA discussion paper was insufficient to facilitate an appropriate level of consultation. In particular Medicines Australia requested access to the consultancy document and costing model prepared for DoHA; and
- there was no information on the process for consultation moving forward.

Medicines Australia has at no point received a response to this submission, nor has it been asked to comment further on any related matter.

Prior to winning the November 2007 election, the then Federal Opposition was on record as questioning the validity of cost-recovery arrangements for the PBS. Between its election victory and the announcement of its first Budget in May 2008, no further information was provided to Medicines Australia or the industry on the intention of the new Government to pursue such a policy.

In its May 2008 Budget, the new Government included cost-recovery in its forward estimates. It also stated that cost-recovery arrangements would commence on July 1, 2008, giving the industry inadequate time to prepare for this additional and substantial cost.

Medicines Australia believes that the introduction of cost-recovery arrangements without appropriate consultation with affected parties is inconsistent with the Government's own Guidelines on cost-recovery. For example, these Guidelines require either a Cost Recovery Impact Statement (CRIS) or a Regulatory Impact Statement (RIS) be prepared prior to the introduction of cost recovery.⁶ Medicines Australia is unaware of the preparation of either such statements.

This is not the only area where Medicines Australia believes that the introduction of the proposed arrangements are, in fact, contrary to the government's own Guidelines and therefore should be abandoned. The remainder of the submission will address this issue.

4 Do the proposed cost-recovery arrangements accord with the Government's own Cost-recovery Guidelines?

In 2002, the Australian Government, in line with recommendations from a Productivity Commission Report⁷, "adopted a formal cost recovery policy to improve the consistency, transparency and accountability of Commonwealth cost recovery arrangements and promote the efficient allocation of resources."⁸

This policy was accompanied by a set of Guidelines, updated in 2005, designed "to provide a framework to assist agencies to design and implement cost recovery arrangements that comply with the cost recovery policy."⁹

Medicines Australia believes that proposed cost-recovery arrangements for the PBS listing process should be assessed against the standards and guidance set out in the Guidelines. Such an assessment will show that the proposal to introduce cost recovery for the PBS is at odds with the Government's own policy on cost recovery generally. This is important because it demonstrates that cost recovery for the PBS is inappropriate.

Of particular importance, these Guidelines require agencies, when determining the appropriateness of introducing cost-recovery measures, to ask the following questions:

- are the proposed arrangements cost-effective?
- are they inconsistent with government policy objectives?

⁶ *Australian Government Cost Recovery Guidelines* p.52

⁷ Productivity Commission 2001, *Cost recovery by Government agencies*, Report no.15, AusInfo, Canberra

⁸ *Australian Government Cost Recovery Guidelines* p.2

⁹ *Australian Government Cost Recovery Guidelines* p.10

- do they unduly stifle competition and industry innovation (for example through ‘free rider’ effects)?¹⁰

In addition to these, the Guidelines also identify the following questions as part of a decision algorithm, where the proposed cost-recovery arrangements are to cover processes related to the products that are regarded as information under the Guidelines of information (as is the case with PBS cost-recovery, as the product of the PBS listing process is a recommendation to the Minister on the listing of a medicine on the PBS):

- do they have ‘public good’ characteristics? and/or
- do they generate significant spillover benefits to the broader community?
or
- are there are other policy reasons for taxpayer funding?¹¹

The Guidelines also require the applying agency to ask whether the introduction of cost-recovery impact on any international obligations?

These are addressed systematically below.

4 (i) Are the proposed arrangements cost-effective?

Medicines Australia does not believe the proposed arrangements for cost-recovery for the PBS listing process meet this test because:

- (a) fees collected will flow into general consolidated revenue and not be adjustable/available to fund process improvements/and or other efficiencies in the PBS listing process itself.
- (b) as argued above **at 3 (a)(ii)**, arguments that the number of re-submissions to the PBAC (that currently characterise the PBS listing process) will be reduced by the imposition of user-pay fees are misguided. The resubmission cycle is driven principally by uncertainty in the interpretation of data and evidence for the purposes of decision-making. The enormous cost already borne by sponsors in the preparation of submissions already serves as an effective disincentive to lodging poor or frivolous submissions for the listing of medicines; it is unlikely that the additional effect of the proposed cost-recovery fees will be to reduce the number of re-submissions.
- (c) As argued above **at 3 (a) (i)** the additional effect of fees as a disincentive will, nonetheless, be significant where this concerns submissions for listings of medicines/indications with small patient populations that Australians need, but which sponsors **already** do not regard as a priority in a commercial environment. This will serve to restrict access to medicines for these patient groups.

4 (ii) Are they inconsistent with government policy objectives?

¹⁰ *Australian Government Cost Recovery Guidelines* p.12

¹¹ *Australian Government Cost Recovery Guidelines* p.30

The PBS, and its listing process, is recognised as the principal mechanism through which the Australian Government achieves a key objective of its National Medicines Policy, ***“the timely access to the medicines that Australians need, at a cost individuals and the community can afford”***.¹²

For reasons described above, the introduction of cost-recovery arrangements will serve to restrict access to medicines for many Australians. Medicines Australia believes that the proposed arrangements serve to undermine the very government policy objectives that the PBS is designed to serve.

4 (iii) Do they unduly stifle competition and industry innovation (for example through ‘free rider’ effects)?

As argued above at 3 (a) (ii), the introduction of the proposed cost-recovery arrangements risk exacerbating existing “free-rider” effects in the PBS listing process that serve to restrict access to medicines, especially when a medicine nears the end of its patent life.

4 (iv) Are there “public good” characteristics of the PBS listing process that, in the absence of a narrowly defined beneficiary, make cost-recovery inappropriate?

Medicines Australia argues that the PBS listing process has “public good” characteristics and therefore should be considered for tax-payer funding in the absence of a narrowly defined group who are the principal beneficiary. The information generated as a result of the original evaluation of a submission is non-excludable as it becomes available for the purpose of decision making for the listing of all subsequent generic versions of that molecule. Essentially, the innovator company is paying for PBAC consideration of a molecule on behalf of itself *and all companies that will introduce other brands of that molecule in the future*. The non-excludable nature of the information that impacts on the decision making process can also extend to different molecules that belong to the same drug class, where the PBAC has deemed such medicines to be “interchangeable at the patient level”. It is this public good characteristic of the PBS listing process that makes the “free rider” effect possible.

Although pharmaceutical companies generate market share through PBS listing, the principal beneficiaries of the PBS listing process itself are (1) the Australian government and (2) the Australian population. The process has been designed to serve these beneficiaries.

¹² The Australian Government, Department of Health and Ageing (2000) *The National Medicines Policy*. Available at [www.health.gov.au/internet/main/publishing.nsf/Content/nmp-objectives-policy.htm/\\$FILE/nmp2000.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/nmp-objectives-policy.htm/$FILE/nmp2000.pdf)

4 (v) Does the PBS listing process generate significant spillover benefits?

Medicines Australia argues the PBS listing process generates significant spillover benefits to the broader Australian community and therefore should be tax-payer-funded. The PBS listing process results in advice on the clinical effectiveness and cost-effectiveness of medicines to the Australian government for the purposes of providing subsidised access to medicines for Australians. It also provides information to clinicians and other medical practitioners on those medicines and recommendations on how they should be used in treating patients in the community. Over time this process has provided equitable access to new medicines as they become available. This has been shown to generate significant health and productivity gains for the Australian population and economy.

4 (vi) Are there other policy reasons that favour tax-payer funding for the process?

As argued above in 2, the PBS listing process is designed to provide advice to the Minister for Health and Ageing to assist the government to make decisions on the most appropriate allocation of scarce health resources within a universal, tax-payer financed health system. Unlike the TGA registration process, the PBS listing process is **not** designed as a mechanism to bring private goods to market. It is difficult to see why the private sector should bear any additional costs (on top of those it already does for the preparation of submissions), for what is essentially a policy level decision to provide Australians with equitable access to health care.

4 (v) Does the introduction of cost-recovery impact on any international obligations?

Medicines Australia considers that the proposal should have regard for Australia's international obligations under the Australia – United States Free Trade Agreement (AUSFTA). The AUSFTA provides for companies to seek an independent review of decisions made by the PBAC. The proposed cost recovery arrangements provide for a fee equivalent to up to \$145,000 to be charged for each independent review conducted.

The Commonwealth Government's Cost Recovery Guidelines advise that the Department of Foreign Affairs and Trade should at the very least be consulted wherever such potential matters arise.¹³ Medicines Australia has not been made aware of any such advice. It is unclear whether the US Government has been informed of the proposed imposition of substantial fees on a process agreed with them as part of the negotiations around the AUSFTA, or whether they agree with the proposed imposition of fees on independent reviews.

¹³ *Australian Government Cost Recovery Guidelines* p.34

5 Conclusion

For the reasons discussed in this submission, Medicines Australia believes that the proposed cost recovery arrangements will have an adverse impact on patient access to medicines, will undermine innovation and create barriers to investment in the Australian pharmaceutical industry and ignores the recent savings to Government and significant impact on industry of the 2007 PBS reform process. Furthermore, utilising the Federal Government's own Cost Recovery Guidelines as a framework for reviewing the proposed introduction of cost recovery for the PBS listing process, it is clear that such cost recovery for the PBS is inappropriate. In the development, introduction and operation of PBS cost recovery there are inconsistencies with the Cost Recovery Guidelines.

For these reasons, Medicines Australia recommends that the Senate reject the proposal.